

From: Schluter, W. William (CDC/CGH/GID)
Sent: Fri, 2 Mar 2018 17:19:31 -0500
To: Craig, Allen (CDC/OID/NCIRD); Cohn, Amanda (CDC/OID/NCIRD)
Subject: FW: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)-
RE: Deaths caused by DTP URGENT PLEASE
Attachments: UNICEF response to ICAN DTP concern 20180212.pdf

Dear Allen/Amanda:

Last week when we met with John and Alejandro, I mentioned this vaccine safety letter that was received by UNICEF and to which UNICEF responded. Just FYI.

Kind regards,
Will

From: Robin Nandy [mailto:rnandy@unicef.org]
Sent: Tuesday, February 13, 2018 11:02 AM
To: Ana Maria Henao-Restrepo <henaorestrepo@icloud.com>
Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; Zuber, Patrick (CDC who.int) <zuberp@who.int>; Wassilak, Steve (CDC/CGH/GID) <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; Mast, Eric (CDC/CGH/GID) <eem1@cdc.gov>; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bww5@cdc.gov>; Vertefeuille, John F. (CDC/CGH/GID) <dki4@cdc.gov>
Subject: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Colleagues

Please find attached letter that went out today. There were substantial delays from our side and multiple reviewers. But happy to let you know that no further changes were made compared to the version we settled on. The only change is that it went out from our Chief of Health rather than our Deputy Executive Director. Given that the content of the letter is technical, there was a feeling among management that it was best for it to go out from the Head of our Health Section.

I will keep you informed if we get a response from Mr Bigtree. I do not think that this is the end of the story. More episodes to come, I'm sure.

Thanks again to you all for your collaboration.

Regards

Robin

Dr. Robin Nandy

Principal Advisor & Chief of Immunizations

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3 United Nations Plaza

New York, NY 10017

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Tel:

Mob:

Email: rnandy@unicef.org

(b)(6)

Date 6 February 2018

Dear Mr Bigtree

Many thanks for your message expressing interest in learning more regarding the safety and effectiveness of the DTP vaccine. I was asked by our outgoing Executive Director, Mr Anthony Lake to prioritize the response to your letter, as he was preparing to leave office, and he asked me to convey his apologies for not responding himself.

I would like to assure you that we take the issue of vaccine safety very seriously. Vaccine safety, along with the safety of all health interventions, are closely followed and monitored by ourselves, in close association with technical agencies like the World Health Organization (WHO). The wellbeing of children, as you are aware, is central to the mandate of UNICEF and we do not compromise in any way in fulfilling this mandate.

There are various independent and multidisciplinary expert bodies at global and national level, which regularly review the evidence on the impact of vaccines and on its safety profile and provide advice to WHO and UNICEF. Notably, the Strategic Advisory Group of Experts (SAGE) is the principal advisory group to WHO for vaccines and immunization (established in 1999). It is charged with advising on overall global policies and strategies, ranging from vaccines (impact and safety) and technology, research and development, to delivery of immunization and its linkages with other health interventions. The Global Advisory Committee on Vaccine Safety (GACVS) responds to vaccine safety issues of potential global importance (established in 1999). The GACVS provides independent, authoritative, scientific advice to WHO on vaccine safety issues of global or regional concern with the potential to affect in the short or long term national immunization programmes. The Immunization and Vaccines Related Implementation Research Advisory Committee (IVIR-AC) provides independent advice on matters related to implementation research and their relevance to immunization policies and practices, and reviews best practices relating to methods for conducting and reporting on quantitative immunization and vaccines-related research (including vaccine impact and safety evaluations).

Some authors have suggested that some of the vaccines routinely administered to infants and children also affect the risk of illness and death from conditions other than the specific infectious diseases they are designed to prevent. The hypotheses concerning these "non-specific effects" of vaccines include that, under some circumstances, some vaccines (for example, measles and Bacillus Calmette-Guérin (BCG)) lower subsequent risk, whereas others (such as DTP) increase subsequent risk of illness and death from other causes. It is further postulated that the magnitude of these effects depends on other factors, including gender and vitamin A supplementation status. The potential for non-specific vaccine effects has led some authors to question whether the vaccination schedules currently recommended by WHO should be adjusted.

WHO with the support of several independent experts has been reviewing and discussing evidence around the non-specific effects of vaccines and immunization programmes since 2001. In 2012, SAGE requested that WHO review the evidence concerning the possible non-specific effects of routine infant vaccines on mortality. A working group was established in March 2013 to review data on non-specific mortality effects and assess whether current evidence is sufficient to inform adjustments in policy recommendations, or if further scientific

investigation is required. A systematic review was conducted to evaluate the non-specific effects on all-cause mortality, in children under 5, of Bacillus Calmette-Guérin (BCG), diphtheria-tetanus-pertussis (DTP), and standard titre measles containing vaccines (MCV); to examine internal validity of the studies; and to examine any modifying effects of gender, age, vaccine sequence, and co-administration of vitamin A.

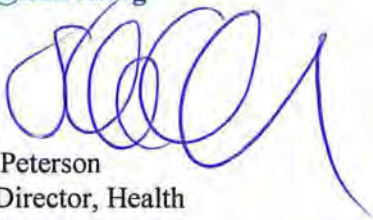
In 2014 SAGE reviewed the outcomes of this review and concluded that, regarding the possible non-specific effect of DTP on all-cause mortality, the available data neither exclude nor confirm the possibility of beneficial or deleterious non-specific effects of DTP vaccines on all-cause mortality. Randomized controlled trials did not contribute any evidence on non-specific effects of DTP. Evidence was largely from observational studies considered at a high risk of bias. Further, SAGE stated that further observational studies are unlikely to contribute to policy decisions. SAGE considered that the non-specific effects on all-cause mortality warranted further research. SAGE recommended that the IVIR- AC be tasked with providing advice on which priority research questions need to be addressed to inform policy decisions, and what kinds of studies and study designs would provide answers to these questions. SAGE concluded that the evidence does not support a change in policy for DTP, and emphasized the benefit of DTP in preventing disease and the importance of the current recommendation.

In conclusion, I would like to reiterate that UNICEF (and WHO) takes the issue of vaccine safety very seriously and for several decades has reviewed the evidence to guide policy decisions. While available evidence does not support a change in DTP vaccination policy, there is substantial evidence on the benefits of DTP (and pentavalent) vaccines in preventing disease and on the substantial risk for unvaccinated population DTP vaccines as evidenced by diphtheria, pertussis and tetanus cases and deaths that we are seeing today. In a number of locations globally, we are experiencing diphtheria outbreaks with high case fatality, which is a direct result of these children not receiving the recommended doses of vaccines in their childhood. Diphtheria, Tetanus and Pertussis were among the leading causes of childhood death in the pre-vaccine era causing several hundred thousand cases each year.

I hope my message provides you with the information that you were seeking. I am copying representatives of our member states who are included in your original message.

Please do not hesitate to contact us if you have further queries or require clarifications. The appropriate point of contact in our office is Dr. Robin Nandy, Principal Advisor and Chief of Immunizations and he can be contacted at rnandy@unicef.org

Sincerely,



Dr. Stefan Peterson
Associate Director, Health
UNICEF Headquarters

From: Schluter, W. William (CDC/CGH/GID)
Sent: Sat, 9 Dec 2017 18:30:34 -0500
To: Cochi, Steve (CDC/CGH/GID); Shefer, Abigail (CDC/CGH/GID); Gidudu, Jane (CDC/CGH/GID); Shimabukuro, Tom (CDC/OID/NCEZID); Destefano, Frank (CDC/OID/NCEZID)
Subject: FW: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP
Attachments: Letter from Informed Consent Action Network (ICAN)- RE Deaths caused by DTP.PDF, Research Paper -Introduction of DTP and Oral Polio Vaccine.pdf
Importance: High

Here's the original.

-----Original Message-----

From: Robin Nandy [<mailto:rnandy@unicef.org>]
Sent: Friday, December 8, 2017 9:56 AM
To: Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>
Subject: FW: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP
Importance: High

Gents

FYI. Will need your assistance in framing an appropriate response.

Regards

Robin

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations UNICEF House
3 United Nations Plaza
New York, NY 10017
USA
Tel: +1-212-326-7612
Mob: +1-917-443-6301
Email: rnandy@unicef.org

-----Original Message-----

From: Robin Nandy
Sent: Thursday, December 7, 2017 5:38 PM
To: FRIEDE, Martin Howell <friedem@who.int>; 'Chang Blanc, Diana (changblancd@who.int)' <changblancd@who.int>
Cc: Benjamin Schreiber (bschreiber@unicef.org) <bschreiber@unicef.org>
Subject: FW: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP
Importance: High

Dear Martin, Diana

Please see message attached which was received by our ED. I was wondering if your DG has received something similar.

In my view, I feel we need to be completely aligned in the way we respond to this. Peter Aaby's work is familiar to

all of us but

(b)(6)

I am at WHO for the Polio PPG meeting tomorrow (Friday, Dec 8) and wonder if you would have a moment for a quick coffee to discuss this further and chart a course of action. Please let me know. My mobile number is in the signature if we are unable to connect in person and have to speak on the phone.

Regards

Robin

(b)(6)
Dr. Robin Nandy
Principal Advisor & Chief of Immunizations UNICEF House
3 United Nations Plaza
New York, NY 10017
USA
Tel:
Mob: (b)(6)
Email: rnandy@unicef.org

From: Destefano, Frank (CDC/OID/NCEZID)
Sent: Thu, 22 Feb 2018 15:13:35 +0000
To: Shefer, Abigail (CDC/CGH/GID)
Subject: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)-
RE: Deaths caused by DTP URGENT PLEASE

Thanks.

Frank DeStefano, MD, MPH

From: Shefer, Abigail (CDC/CGH/GID)
Sent: Wednesday, February 21, 2018 2:52 PM
To: Destefano, Frank (CDC/OID/NCEZID) <fxd1@cdc.gov>
Cc: Shimabukuro, Tom (CDC/OID/NCEZID) <ayv6@cdc.gov>
Subject: Fwd: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Whoops. Frank I think I got wrong email for you...

From: Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>
Date: February 21, 2018 at 2:50:00 PM EST
To: Shimabukuro, Tom (CDC/OID/NCEZID) <ayv6@cdc.gov>, DeStefano, Frank (NIP) <CORP/NIP1/fxd1@cdc.gov>
Subject: Fwd: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

FYI. I don't know if this was ever shared with you.

From: Robin Nandy <rnandy@unicef.org>
Date: February 13, 2018 at 11:05:01 AM EST
To: Ana Maria Henao-Restrepo <henaorestrepoa@icloud.com>
Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>, hombachj@who.int <hombachj@who.int>, Zuber, Patrick (CDC who.int) <zuberp@who.int>, Wassilak, Steve (CDC/CGH/GID) <sgw1@cdc.gov>, Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>, Diana Chang Blanc <changblancd@who.int>, Martin Howell FRIEDE <friedem@who.int>, Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>, Mast, Eric (CDC/CGH/GID) <eem1@cdc.gov>, Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>, Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>, Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>, Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>, Vertefeuille,

John F. (CDC/CGH/GID) <dk4@cdc.gov>

Subject: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Colleagues

Please find attached letter that went out today. There were substantial delays from our side and multiple reviewers. But happy to let you know that no further changes were made compared to the version we settled on. The only change is that it went out from our Chief of Health rather than our Deputy Executive Director. Given that the content of the letter is technical, there was a feeling among management that it was best for it to go out from the Head of our Health Section.

I will keep you informed if we get a response from Mr Bigtree. I do not think that this is the end of the story. More episodes to come, I'm sure.

Thanks again to you all for your collaboration.

Regards

Robin

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations
UNICEF House

3 United Nations Plaza
New York, NY 10017

USA

Tel:

Mob:

Email:

From: Ana Maria Henao-Restrepo [<mailto:henaorestrepo@icloud.com>]

Sent: Friday, January 26, 2018 3:16 PM

To: Robin Nandy <rnandy@unicef.org>

Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dk4@cdc.gov>

Subject: Re: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin,

Thanks to you for this very inclusive and collaborative effort!

Warm regards

Ana María

Sent from my iPhone

On 26 Jan 2018, at 20:56, Robin Nandy <rnandy@unicef.org> wrote:

Thanks Ana Maria and Will

Hope this is okay, Will?

Please find attached final draft which I am sending 'up'.

I will circulate the final signed version when it does go out.

I would like to reiterate how much I appreciate WHO and CDC guidance and inputs on this.

Good weekend all.

Regards

Robin

Dr. Robin Nandy
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UNICEF House
3 United Nations Plaza
New York, NY 10017
USA
Tel: +1-212-326-7612
Mob: +1-917-443-6301
Email: rnandy@unicef.org

From: Ana Maria Henao-Restrepo [<mailto:henaorestrepo@icloud.com>]

Sent: Friday, January 26, 2018 1:01 PM

To: Robin Nandy <rnandy@unicef.org>

Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; Cochi, Steve (CDC/CGH/GID)

<slc1@cdc.gov>; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dk4@cdc.gov>

Subject: Re: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin,

Yes we believe this statement is important as it accurately reflect the conclusions from the SAGE and the evidence findings

Our preference is therefore for it to remain...

Kind regards
Ana María

Sent from my iPhone

On 26 Jan 2018, at 16:50, Robin Nandy <rnandy@unicef.org> wrote:

Dear **Will and Steve (Cochi)**

Many thanks for your prompt responses. On your two comments, the second one is straightforward and I will incorporate in the next iteration.

On your first comment on the sentence reading "***Regarding the possible non-specific effect of DTP on all-cause mortality, the available data neither exclude nor confirm the possibility of beneficial or deleterious non-specific effects of DTP vaccines on all-cause mortality.***"

I think Ana Maria was keen to include this as it is the language used in the SAGE review and the need to have language in the letter consistent with it. However, I will look forward to additional comments, particularly from WHO colleagues.

Ana Maria, Martin

Your thoughts and guidance please.

Again, thanks to all for their patience on the multiple back and forth on this. I feel we are nearly there 😊

Regards

Robin

Dr. Robin Nandy

Principal Advisor & Chief of Immunizations
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Tel: +1-212-326-7612
Mob: +1-917-443-6301
Email: rnandy@unicef.org

From: Schluter, W. William (CDC/CGH/GID) [<mailto:wbs8@cdc.gov>]
Sent: Friday, January 26, 2018 8:42 AM
To: Robin Nandy <rnandy@unicef.org>; Ana Maria Henao-Restrepo <henaorestrepo@icloud.com>
Cc: hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dk4@cdc.gov>
Subject: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin:

Sorry, if I am raising issues you've already considered. Two minor edits noted in the attached. Overall, the message is clear and powerful.

Kind regards,

Will

From: Robin Nandy [<mailto:rnandy@unicef.org>]
Sent: Friday, January 26, 2018 5:49 AM
To: Ana Maria Henao-Restrepo <henaorestrepo@icloud.com>
Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; Zuber, Patrick (CDC who.int) <zuberp@who.int>; Wassilak, Steve (CDC/CGH/GID) <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; Mast, Eric (CDC/CGH/GID) <eem1@cdc.gov>; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; Vertefeuille, John F. (CDC/CGH/GID) <dk4@cdc.gov>
Subject: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE
Importance: High

Dear Ana Maria, Steve and Will

Many thanks for your inputs. Please be assured that your inputs are very much appreciated and the letter is based on the inputs provided previously. The aim of additional edits was to reduce

length, ensure flow and keep it focused and to the point while retaining language consistent with SAGE recommendations. Your current round of inputs really helps to get us there.

Please find herewith, the next iteration based on your comments. I would appreciate your review and endorsement of this version following which I will submit it to our Executive Office. As mentioned earlier, I would like both WHO and CDC to be comfortable with the content of this letter.

I truly appreciate your support in this process.

Regards

Robin

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Email: rnandy@unicef.org

From: Ana Maria Henao-Restrepo [<mailto:henaorestrepo@icloud.com>]

Sent: Wednesday, January 24, 2018 7:49 AM

To: Robin Nandy <rnandy@unicef.org>

Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; slc1@cdc.gov; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Laura Conklin (CDC/OID/NCIRD) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dk4@cdc.gov>

Subject: Re: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin,

Thanks for sharing this revised version.

We fully understand the need for internal clearance and buy in at UNICEF.

However, please allow us to provide some additional comments.

As stated by you there are 'sensitivities' and we believe our strength comes from the independent evidence based process that we all have followed and adhere to.

Therefore, the attached comments are suggestions to use same or similar language to that of SAGE and to also ensure any detail technical comments is aligned with what the conclusions of the review are.

(I have spend over 4 years on this topic and come to realise how critical this is.)

As stated in the document we are not proposing that all the text is included but that key proposed terms (in bold) are maintain throughout.

We trust you received these comments in the constructive spirit that inspired them.

Kind regards,

Ana Maria

On 24 Jan 2018, at 13:01, Robin Nandy <rnandy@unicef.org> wrote:

Dear Colleagues

As you can imagine, given the sensitivities with this letter, it has gone through extensive review inhouse. Attached herewith is the latest iteration.

We have tried to ensure that the main messages are retained and the letter is factually accurate based on extensive inputs provided by yourselves.

Could you take a quick read to see if you are comfortable with this version and if you would like to see any changes. We are all implicated in this and I want to ensure that you are all comfortable with the content.

We would like to have closure on this asap - it has already dragged on far too long, largely due to the process on our end.

I look forward to hearing from you.

Regards

Robin

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations
UNICEF House
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USA
Tel: +1-212-326-7612
Mob: +1-917-443-6301
Email: rnandy@unicef.org

From: Ana Maria Henao-Restrepo [<mailto:henaorestrepa@icloud.com>]
Sent: Monday, January 8, 2018 6:43 PM
To: Robin Nandy <rnandy@unicef.org>
Cc: Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>; hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Diana Chang Blanc <changblancd@who.int>; Martin Howell FRIEDE <friedem@who.int>; slc1@cdc.gov; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Laura Conklin (CDC/OID/NCIRD) <dvj3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dk14@cdc.gov>
Subject: Re: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin,

Please find attached a proposed revised version of the letter for your consideration.
In brief, I have added statements re benefits of DTP and revised the TORs and roles of the various WHO committees.
Moreover, the text regarding the recommendations was adjusted to be more aligned -in my view- the original recommendations.

I hope this is helpful.

Other colleagues will certainly add additional comments or modifications.

Kind regards,

Ana Maria

(PS Happy 2018 to all..!)

On 29 Dec 2017, at 19:54, Robin Nandy <rnandy@unicef.org> wrote:

Thanks Will. I will look forward to further inputs from colleagues. At our end, we are thinking that the counterfactual argument may also be worth making - the potential impact on not using the DTP vaccine.

I guess many colleagues are on leave and it is also after hours in Geneva - so we will have to pick it up in the new year.

Here's wishing all colleagues a very happy, successful and prosperous new year.

Regards

Robin

Dr. Robin Nandy
Principal Advisor & Chief of Immunizations
UNICEF House
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Tel: (b)(6)
Mob: (b)(6)
Email: rnandy@unicef.org

From: Schluter, W. William (CDC/CGH/GID) [<mailto:wbs8@cdc.gov>]
Sent: Friday, December 29, 2017 9:34 AM
To: Robin Nandy <rnandy@unicef.org>; HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; hombachj@who.int; zuberp@who.int; Steve Wassilak <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>
Cc: Diana Chang Blanc <changblancd@who.int>; FRIEDE, Martin Howell <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; eem1@cdc.gov; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvi3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; John Vertefeuille <dkl4@cdc.gov>
Subject: RE: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths caused by DTP URGENT PLEASE

Dear Robin:

I agree with your assessment that the letter may need to be strengthened in the third paragraph. I'll leave it to others to suggest specific language.

Kind regards,
Will

From: Robin Nandy [<mailto:rnandy@unicef.org>]
Sent: Thursday, December 28, 2017 4:15 PM
To: HENAO RESTREPO, Ana Maria <henaorestrepoa@who.int>; hombachj@who.int; Zuber, Patrick (CDC who.int) <zuberp@who.int>; Wassilak, Steve (CDC/CGH/GID) <sgw1@cdc.gov>; Fox, Kimberley (CDC/CGH/GID) <kaf6@cdc.gov>; Schluter, W. William (CDC/CGH/GID) <wbs8@cdc.gov>
Cc: Diana Chang Blanc <changblancd@who.int>; FRIEDE, Martin Howell <friedem@who.int>; Cochi, Steve (CDC/CGH/GID) <slc1@cdc.gov>; Mast, Eric (CDC/CGH/GID) <eem1@cdc.gov>; Shefer, Abigail (CDC/CGH/GID) <ams7@cdc.gov>; Conklin, Laura (CDC/CGH/GID) <dvi3@cdc.gov>; Kerr, Yinka (CDC/CGH/GID) <yak2@cdc.gov>; Gidudu, Jane (CDC/CGH/GID) <bwv5@cdc.gov>; Vertefeuille, John F. (CDC/CGH/GID) <dkl4@cdc.gov>
Subject: RE: RE: OED/2017-01818 : Letter from Informed Consent Action Network (ICAN)- RE: Deaths

caused by DTP URGENT PLEASE

Importance: High

Dear Ana Maria, Joachim, Patrick, Steve, Kim and Will

I know that many of you may be on leave this week. However, I wanted to update you on where the letter in response to the ICON letter on child deaths due to DTP is at.

Attached is the most current version in the final stages of clearance in our Executive Office. I also attach the version that was developed with your inputs, which I am indeed grateful for.

Reading this attached version, we are feeling that the response may not be strong enough. Can we provide further details on why we cannot prove or disprove this claim despite the fact that this issues has been followed since 2001, the lack of RCT on the NSE of DTP and also what the status of ongoing research on the subject is? Can we strengthen the response so that we do not leave ourselves open to additional questions and criticisms. Also, our response is likely to be posted on the ICON website.

Any further inputs and thoughts you may have will be much appreciated. We would like to finalize and send out the response asap as country missions, notably the Nigeria mission have inquired how UNICEF is going to respond to this message.

Regards

Robin

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<ED Response DTP Dec 2017 DRAFT4.docx>

<ED Response DTP Dec 2017 FINAL DRAFT.docx>